121

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,019	02/15/2001	Alexander Gaiger	210121.465C4	3923

500 7590 05/18/2004

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,019	GAIGER ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7 and 47-54* is/are pending in the application.

4a) Of the above claim(s) *3 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,47,48 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of Group I and the species SEQ ID N0:335 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

2. Claims 10-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

3. Applicant's election of Group I in the paper received 8/27/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the paper filed 8/27/2003.

5. Applicant's election with traverse of the peptide of claim 48 and microspheres in the paper filed 8/27/2003 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments, said peptides are distinct because they are of differing lengths and different amino acid sequences.

The requirement is still deemed proper and is therefore made FINAL.

6. Claim 49 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 8/27/2003.

7. Claims 1,2,6,7,47,48,50-54 are under consideration.

8. Regarding applicants claim to priority in page 1 of the specification, "related" is not an appropriate term to indicate a priority claim. Page one of the specification should be amended to recite "This application is a CIP of U.S. Patent Application No. 09/685, 830, filed October 9, 2000 which is a CIP of U. S. Application No. 09/684,361, filed October 6, 2000; which is a CIP of U.S. Application No. 09/276,484, fled March 25, 1999; which is a CIP of U.S. Application No. 09/164,223, filed September 30, 1998 ...".

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

9. The "WT1" recited in claim 48 is interpreted as referring to the peptide of SEQ ID NO 335 in claim 1 or 47 (eg. wherein said sequence is a "WT1"). Therefore, said claim refers to amino acids in SEQ ID NO 335.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 48,50,52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the peptide of claim 48. The claim recites a peptide from WT1 wherein said claim depends from the WT1 peptide of SEQ ID NO 335. While the specification discloses the claimed peptide derived from *native* WT1 (wherein the cited residues are found in said position of native WT1), SEQ ID NO 335 is not drawn to native WT1, it is a WT1 polypeptide with a His tag at the N terminal. Thus, position 117-139 in SEQ ID NO 335 is not position 117-139 of native WT1 (because of the added His tag at the N terminal) and there is no disclosure in the specification as originally filed of a peptide derived from amino acids 117-139 in SEQ ID NO 335.

There is no support in the specification as originally filed for the peptide of claim 50. The specification does disclose a his tag fusion protein SEQ. ID. NO 335. The specification does not disclose what residues of said peptide constitute the his tag portion of the fusion protein. Assuming the his tag encompasses only the 6 his residues at positions 3-8 of SEQ ID NO 335, removal of said residues would leave a peptide containing residues 1,2,9-256 of SEQ ID NO 335 wherein there is no disclosure of such a peptide in the specification as originally filed.

There is no disclosure in the specification as originally filed of an "immunogenic composition" with the ingredients recited in claims 52-54. The specification does disclose vaccine compositions with said ingredients.

There is no written description of the scope of the claimed inventions in t he specification as originally filed (eg. the claimed inventions constitute new matter).

12. Claims 1,2,6,7,50-54 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds MHC of an animal (eg. T cell reacting requires binding of the peptide to an MHC molecule on an antigen presenting cell which presents the antigen to the T cell). The claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds antisera against WT1. There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description of specific variants only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. The specification only discloses peptides which bind a limited subset of known human HLA alleles. Similarly, the specification provides written description of particular peptides that bind WT1 antisera. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA

which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC or WT1 antisera, while claiming peptides which bind any MHC or antisera against WT1 from any mammal. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

13. Claims 47,50-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims encompass a variant peptide with one to three substitutions wherein said peptide encodes an immunogenic peptide wherein said peptide binds MHC of an animal (eg. T cell binding requires MHC binding of the peptide). There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description of specific variants only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. The specification only discloses peptides which bind a limited subset of known human HLA alleles. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids

species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC, while claiming peptides which bind any MHC from any mammal. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

14. Regarding priority of the claims under consideration and the application of prior art, the peptide of SEQ. ID. NO 335 is not disclosed in any of the parent applications to which priority is claimed and therefore the effective filing date of the instant claims is that of the instant application.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1,2,6,7,47,48,50,51 are rejected under 35 U.S.C. 102(b) as being anticipated by Herlyn et al. (WO 95/29995).

Herlyn et al. teach an immunogenic peptide containing amino acids derived from amino acids 1-181 of human WT1(see page 19, last paragraph and peptide recited in claim 16), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). SEQ. ID. No 335 is a human WT1. The pharmaceutically acceptable excipient is the buffer that said peptide is dissolved in (see page 20, example 2).The peptide of claim 48 is found in the human WT1 taught by Herlyn et al. (see SEQ. ID. No 2). The peptide inherently contains an MHC class I binding peptide (it contains amino acids 1-181 wherein numerous MHC class I peptides are present in said region as per disclosed in the specification of the instant application). The peptide recited in claim 16 of Herlyn et al. does not contain a his tag.

17. Claims 1,2,6,7,47,50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al. (WO 00/06602) as evidenced by EP1103564.
EP1103564 is an English language version of WO 00/06602 (they have the same figures, peptides, sequences, filing date, etc.). Sugiyama et al. disclose immunogenic human MHC class I binding 9mer peptides derived from amino acids found in WT1 (see page 6, SEQ ID NO 5 and 8, and page 8 and SEQ. ID. No 2)(page 4 of EP1103564) wherein both peptides are found in SEQ. ID. N0 335. Said peptides are

immunogenic (they serve as a target for CTL lysis, see Figures 2-4, wherein EP 1103564 discloses the English language captions for said Figures). Sugiyama et al. disclose compositions containing said peptides and a pharmaceutically acceptable carrier (see pages 8 and 9 (as per page 5, lines 1-16 of EP 1103564). Sugiyama et al. disclose compositions containing said peptides and a microsphere (AKA liposome, see pages 8 and 9 (as per page 5, lines 1-16 of EP 1103564). The specification discloses that microspheres have the property recited in claim 53 (see page 40, penultimate paragraph).

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1,2,6,7,47,48,50-54 are provisionally rejected under the judicially created doctrine of double patenting over claims 1,6,7,46-51,55,57,59-62 of copending Application No. 09/684361. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that

copending application since the referenced copending application and the instant application are claiming common subject matter, as follows. While the two sets of claims differ in scope, both sets encompass similar peptides and compositions (the peptide of claim 1 of 09/684361 is found in SEQ. ID. No 335).

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

20. Claims 1,2,6,7,47,50-54 are provisionally rejected under the judicially created doctrine of double patenting over claims 104,107-112 of copending Application No. 09/16423. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows. While the two sets of claims differ in scope, both sets encompass similar peptides and compositions (the peptide of claim 104 is found in SEQ. ID. No 335).

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 730am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax

phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1600~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644